HFI-35
Purged
d1194b

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
781.279.1675 FAX: 781.279.1742

June 15, 1998

NWE-13-98W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Baltej Maini,
President and CEO
The Fallon Clinic
100 Central Street
Worcester, MA 01608

Dear Dr. Maini:

During an inspection of your home respiratory care (HRC) company (The Fallon Clinic / Lakeview Medical, Inc. 100 Hartwell Street, West Boylston, MA) on May 21, 27, and June 1, 1998, our investigator determined that liquid medical oxygen is being transfilled into cryogenic home units and distributed. This medical gas is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that this drug is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to Current Good Manufacturing Practice Regulations for drugs specified in Title 21 Code of Federal Regulations, Parts 210 and 211. Deviations documented by our investigator (see enclosed copy of Form FDA 483) and presented to Mr. Steven Penka, Assistant Administrator include:

- Failure to properly assay the incoming liquid oxygen for identity and strength prior to filling the cryogenic home units.

  The need for testing cryogenic home units is obviated ***only under certain conditions***—liquid oxygen must be the only liquefied gas being filled on site; the

incoming liquid oxygen must have been ***adequately*** tested for identity and strength; and the home units must be filled and retained by your firm.

Adequate testing of the large cryogenic vessels of incoming liquid oxygen can be demonstrated in one of the following ways:

a. if a ***trained*** representative of your firm ***witnesses*** your supplier's testing (for identity *and* strength), receives a ***valid*** certificate of analysis (COA), and ***documents*** that the testing has been witnessed. The minimum information that should be provided in a valid COA is as follows:

   1. supplier's name
   2. name of product
   3. air-liquefaction statement
   4. lot number or other unique identification number
   5. actual analytical results for identity and strength
   6. test method used (letter on file from supplier is acceptable)
   7. supplier's signature and date

   The training received by your firm's representative must be documented.

b. if, for those instances when the testing is ***not witnessed***, a valid COA is obtained and an identity test is performed on each large cryogenic vessel received or filled. The reliability of the supplier's analysis must be verified periodically—preferably annually—by:

   1. full USP testing of a recently delivered vessel by a third party, or

   2. verifying the supplier's analysis by:

      i. confirming that the supplier is registered with FDA

      ii. confirming that the supplier is following appropriate written procedures

      iii. witnessing the testing, including any calibration, and

      iv. documenting these steps

c. If your firm neither witnesses the testing nor obtains a valid COA, full USP testing is required for each cryogenic vessel delivered by your supplier.

Your firm has never verified your suppliers' testing; has not documented any employee training; and, prior to this inspection, had neither maintained records of identity testing, nor developed written procedures for conducting these identity tests.

In addition, the transfilled liquid oxygen is misbranded in that it was manufactured in an establishment not duly registered under Section 510 of the Act and the article has not been listed as required by Section 510(j). The Act requires fillers of medical gases to register *annually* with FDA.

The letter dated June 5, 1998 from Mr. John J. DiGiorgio responding to the list of inspectional observations (Form FDA 483) has been reviewed. This response is less than fully adequate in that:

- The draft procedure *Oxygen Supplier Analysis Verification* does not include confirmation of supplier registration with FDA.

- The draft procedure entitled *Liquid Oxygen Filling—Patient Location* has no provision for the performance of a label inspection. All medical gas drug labeling for prescription products must include:

  a. the name and place of business of the manufacturer, packer, or distributor

  b. the official product name and a statement of quantity of contents

  c. adequate directions for use

  d. a statement regarding air liquefaction

  e. the statement: "Caution: Federal law prohibits dispensing without a prescription."

  f. a lot number

  g. a statement of ingredients (for gas mixtures)

  Prefill inspections of cryogenic home vessels should be entered on an appropriate batch production record.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action by FDA without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Mark Lookabaugh, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at 781.279.1675 ext. 118.

Sincerely,

John Marzilli
Director
New England District

Enclosure

cc:
Steven Penka, Assistant Administrator
John J. DiGiorgio, Manager, Durable Medical Equipment and Respiratory Services
The Fallon Clinic
d/b/a Lakeview Medical, Inc.
100 Harwell Street
West Boylston, MA 01583